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Ezio Bombardelli

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EXAMINER

MI, QIUWEN

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/563,965 | Applicant(s) BOMBARDELLI, EZIO | |
| | Examiner QIUWEN MI | Art Unit 1655 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-10 and 13 is/are pending in the application.
- 4a) Of the above claim(s) 3,6-8 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,9 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment in the reply filed on 4/14/07 is acknowledged. Any rejection that is not reiterated is hereby withdrawn.

Claims Pending

Claims 5, 11, and 12 are cancelled. Claims 1-4, 6-10, and 13 are pending. Claims 3, 6-8, and 10 are withdrawn as they are directed toward a non-elected invention groups or species. Claims 1, 2, 4, 9, and 13 are examined on the merits.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 9, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Di Pierro (WO 02/098436 A1), and Znaiden et al (US 5,523,090).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 12/13/2007, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Di Pierro discloses a pharmaceutical and/or cosmetic composition for the treatment of cellulite comprising 0.1-2.5% complex of escin/beta-siterol with phospholipids (the third

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vasoactive agent), 0.1-2.5% complex of *Ginkgo biloba* dimeric flavonoids with phospholipids (the second vasoactive agent) etc (page 2, lines 20-28). Di Pierro also teaches that the complex of escin/beta-sitosterol with phospholipids has the same action as escin, but shows a more prolonged release of the active principles and improved bioavailability (page 3, lines 10-13); and the complex of *Ginkgo biloba* dimeric flavonoids with phospholipids, has the same activity as the dimeric *Ginkgo biloba* flavones in the free form, but shows a more prolonged release of the active principles and better bioavailability. *Ginkgo biloba* dimeric flavonoids are extremely potent vasoactive agents due to their inhibitory action on the release of histamine and of the enzyme cAMP phosphodiesterase from mast cells (page 3, lines 13-20). Di Pierro further teaches that the composition of the invention will be formulated in the form of cream, oil, gel, foam, emulsion, milk (page 4, lines 15-20).

Di Pierro does not teach the incorporation of the first vasoactive agent visnadin into the composition.

Znaiden et al disclose an anti-cellulite composition comprising Ginkgo biloba extract (the second vasoactive agent), escin (the third vasoactive agent) etc (col 12, Example 10). Znaiden et al teach that various types of active ingredients may be present in the present invention (col 6, lines 53-56). Suitable vasoactive compounds include but not limited to visnadin etc (col 7, lines 10-15). Znaiden et al also suggest that the topical skin treatment composition of the invention can be formulated as a lotion, a fluid cream, and a gel (col 8, lines 58-67, bridging col 9, lines 1-5).

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that it is deemed that the prior art product must

not be precluded for use as a vasoactive agent. It is deemed that the composition disclosed by Di Pierro and Znaiden et al. is not precluded for carrying out the intended function of the claims.

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ...[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.).

In the instant case, all of the above-listed ingredients were known for treating cellulites. Thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial in treating cellulites.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for treating cellulites. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, In re Sussman, 1943 C.D. 518.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 220 F.2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the amounts of each constituent as in the claims, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was

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made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to combine the inventions of Di Pierro and Znaiden since both of them teach topical compositions for treating cellulites individually in the art. Since both of the compositions yielded beneficial results in treating cellulite, one of ordinary skill in the art would have been motivated to make the modifications.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Regarding the inventor names “Bombardelli and Cho et al” on page 5 of the previous office action, it was a typo, which has already been changed to “Di Pierro and Znaiden et al”.

Applicant presents the data of the declaration filed on 5/30/07, and argues that the unexpected result should have been considered (pages 3 and 4).

According to MPEP 716.02 (a), an unexpected result should be a side by side comparison between the closest cited art, and the claimed invention. In the instance case, the closest art Di

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Pierro teaches a composition comprising escin/beta-siterol and *Gingko biloba* dimeric flavonoids with phosphalipids. Therefore, Applicant should have compared the claimed invention with the composition of Di Pierro. However, none of the groups in page 2 of the declaration includes the composition of escin/beta-siterol and *Gingko biloba* dimeric flavonoids with phosphalipids (without visnadin). In addition, according to Table 2 on page 4 of the declaration, the thigh circumference (cm) after administration of the claimed invention reduced from 56.4 cm to 53.2 cm, and there is no significant difference between the before and after treatment data. Therefore, the affidavits under 37 CFR 1.132 filed on 5/30/07 is insufficient to overcome the rejection of claims.

Applicant also argues that visnadin is indicated as one of the many optional ingredients that may be present in the cosmetic composition (page 5, 2nd paragraph). Applicant further argues that one of ordinary skill in the art faced with the problem of finding an effective anti-cellulite composition would not have seriously contemplated using visnadin (page 5, 3rd paragraph).

This is not found persuasive. Znaiden et al teach skin treatment for reducing signs of cellulite (see Abstract). Znaiden et al clearly state that “suitable vasoactive compounds include but are not limited to papaverinc, yohimbine, visnadin, khelin, bebelin, nicotinate derivatives” (col 7, lines 10-15). It is well known in the art that vasoactive compounds have been used successfully in treating cellulite, and at least decades of patent publications have the subject matter of treating cellulite with vasoactive compounds. Therefore, one of the ordinary skills in the art would have use the visnadin as a suitable compound in the treatment of cellulite as taught by Znaiden et al.

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Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QM

/Christopher R. Tate/
Primary Examiner, Art Unit 1655